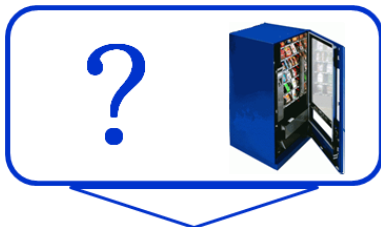




CE Marking Process

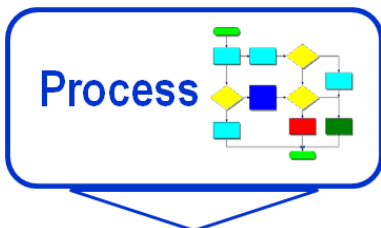


1. Initial Review: During this phase it is important to consider the details of the product i.e. What is it? What is it intended to do? Who would use it? Where would it be used? Are there any alternative applications?

We have been doing this for years and often do this stage are part of the introductory consultation.

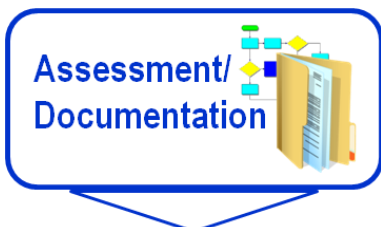


2. Applicable EU Directives: From the above the likely "CE Marking" directives can be identified. Quite a few products fall within the scope of more than one directive, and you have to show compliance with all that apply. In some cases it is (almost) equally important to justify why a product is considered to be outside the scope of a particular directive.



3. Conformity Assessment Procedure: Depending on the applicable directives and the particulars of the individual product, it is necessary to determine the Conformity Assessment Procedure that needs to be applied. In many cases the Manufacturer can carry out the process (often with our help), however some higher risk products require the involvement of a Notified Body at some stage.

At this stage it is sensible to define the details of the process to be used, this may include the identification of suitable harmonized standards.



4. Assessment and documentation: Based on the above, the main part of the work is to identify the hazards and risks associated with the product and to carry out an assessment with respect to the detailed requirements of the applicable directives (and standards if applicable). The result of the process is a detailed set of technical documentation (often called a technical file or technical construction file) which provides the means of demonstrating compliance. It should be noted that the requirements for technical documentation vary between directives. We have many years experience in this area and can product a range of assistance from general guidance to detailed technical file production.

User Manuals



5. User Manuals: It is usually necessary to provide some form of user documentation (possibly assembly and installation information as well), this could be anything from simple instructions on the product or packaging, through to detailed user and service manuals. These documents form part of the support information for the CE marking and should be suitably controlled.

Some directives (and standards) specify the minimum content of such documents. We have experience of reviewing, modifying client documentation and in some cases, of producing the documents from scratch.

D.o.C



6. Declaration of Conformity: Once all technical documentation is in place, the Manufacturer (or Authorized representative in the EU) produces a Declaration of Conformity stating the products compliance with the requirements of the applicable directives. This must be signed by a "responsible person".

CE



7. Affixing the CE marking: When the above stages are complete the CE Marking is applied to the product. This indicates to the authorities that a Declaration of Conformity has been signed and that all appropriate support information is available for review if required.

Other information is generally required to be on the product, the requirements vary depending on the directive.

Production Control



8. Control of production: Completing the above process provides the necessary information to show that the reviewed product complies with the requirements of the identified directives. To ensure that all of the products made comply it is necessary to have suitable controls on the various stages of production.

We have detailed experience of helping clients establish suitable processes to show that they comply. These range from basic controls through to ISO 9001 and ISO 13485 systems.

petts consulting

Tel: 01825 767188

Email: contactus@petts-consulting.co.uk

Web: www.petts-consulting.co.uk

